

consecutive month cost reports for the 3 cost reporting years preceding the payment year to verify the number of treatments, except that:

(1) In the case of a hospital-based ESRD facility as defined in § 413.174(c), the MAC relies upon the attestation submitted pursuant to paragraph (e) of this section and may consider other supporting data in addition to the total treatments reported in each of the 12-consecutive month cost reports for the 3 cost reporting years preceding the payment year to verify the number of treatments that were furnished by the individual hospital-based ESRD facility seeking the adjustment; and

(2) In the case of an ESRD facility that has undergone a change of ownership that does not result in a new Provider Transaction Access Number for the ESRD facility, the MAC relies upon the attestation and when the change of ownership results in two non-standard cost reporting periods (less than or greater than 12-consecutive months), does one or both of the following for the 3 cost reporting years preceding the payment year to verify the number of treatments:

(i) Combines the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period; and/or

(ii) Combines the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorates the data to equal a full 12-consecutive month period.

[75 FR 49200, Aug. 12, 2010, as amended at 76 FR 70314, Nov. 10, 2011; 79 FR 66262, Nov. 6, 2014; 80 FR 69076, Nov. 6, 2015]

§ 413.233 Rural facility adjustment.

CMS adjusts the base rate for facilities in rural areas, as defined in § 413.231(b)(2).

[80 FR 69077, Nov. 6, 2015]

§ 413.234. Drug designation process.

(a) *Definitions.* For purposes of this section, the following definitions apply:

ESRD PPS functional category. A distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or manage-

ment of a condition or conditions associated with ESRD.

New injectable or intravenous product. An injectable or intravenous product that is approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, assigned a Healthcare Common Procedure Coding System code, and designated by CMS as a renal dialysis service under § 413.171.

Oral-only drug. A drug or biological with no injectable equivalent or other form of administration other than an oral form.

(b) *Drug designation process.* Effective January 1, 2016, new injectable or intravenous products are included in the ESRD PPS bundled payment using the following drug designation process:

(1) If the new injectable or intravenous product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or intravenous product is considered included in the ESRD PPS bundled payment and no separate payment is available.

(2) If the new injectable or intravenous product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or intravenous product is not considered included in the ESRD PPS bundled payment and the following steps occur:

(i) An existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or intravenous product is used to treat or manage;

(ii) The new injectable or intravenous product is paid for using the transitional drug add-on payment adjustment described in paragraph (c) of this section; and

(iii) The new injectable or intravenous product is added to the ESRD PPS bundled payment following payment of the transitional drug add-on payment adjustment.

(c) *Transitional drug add-on payment adjustment.* (1) A new injectable or intravenous product that is not considered included in the ESRD PPS base rate is paid for using a transitional

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drug add-on payment adjustment, which is based on pricing methodologies under section 1847A of the Social Security Act.

(2) The transitional drug add-on payment adjustment is paid until sufficient claims data for rate setting analysis for the new injectable or intravenous product is available, but not for less than two years.

(3) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will be modified, if appropriate, to account for the new injectable or intravenous product in the ESRD PPS bundled payment.

(d) *Oral-only drug determination.* An oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the Food and Drug Administration.

[80 FR 69077, Nov. 6, 2015]

§ 413.235 Patient-level adjustments.

Adjustments to the per-treatment base rate may be made to account for variation in case-mix. These adjustments reflect patient characteristics that result in higher costs for ESRD facilities.

(a) CMS adjusts the per treatment base rate for adults to account for patient age, body surface area, low body mass index, onset of dialysis (new patient), and co-morbidities, as specified by CMS.

(b) CMS adjusts the per treatment base rate for pediatric patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act, to account for patient age and treatment modality.

(c) CMS provides a wage-adjusted add-on per treatment adjustment for home and self-dialysis training.

[75 FR 49201, Aug. 12, 2010]

§ 413.237 Outliers.

(a) The following definitions apply to this section.

(1) *ESRD outlier services* are the following items and services that are included in the ESRD PPS bundle:

(i) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

(ii) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

(iii) Medical/surgical supplies, including syringes, used to administer ESRD-related drugs that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and

(iv) Renal dialysis services drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including ESRD-related oral-only drugs effective January 1, 2025.

(v) As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

(2) *Adult predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to an adult beneficiary by an ESRD facility.

(3) *Pediatric predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to a pediatric beneficiary by an ESRD facility.

(4) *Adult fixed dollar loss amount* is the amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to an adult beneficiary must exceed the adult predicted ESRD outlier services MAP amount to be eligible for an outlier payment.

(5) *Pediatric fixed dollar loss amount* is the amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to a pediatric beneficiary must exceed the pediatric predicted ESRD outlier services MAP amount to be eligible for an outlier payment.

(6) *Outlier Percentage:* This term has the meaning set forth in § 413.220(b)(4).

(b) *Eligibility for outlier payments—(1) Adult beneficiaries.* An ESRD facility will receive an outlier payment for a treatment furnished to an adult beneficiary if the ESRD facility's per-treatment imputed MAP amount for ESRD outlier services exceeds the adult predicted ESRD outlier services MAP